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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,499	07/26/2001	David Hung	05284.00096	6261

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,499

Applicant(s)

HUNG, DAVID

Examiner

Kathryn L Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/04/02.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 26, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07/26/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5, 12, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hung (US 6,413,228). Hung discloses a device (Figure 4A) for collecting breast duct fluid from within a breast duct in order to detect breast cancer or precancer comprising a probe having a diameter sized to penetrate a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, wherein said probe is free of a connection for a fluid source or lumen (Column 19, Lines 31-33), wherein said diameter of said probe is between about 0.008 cm and about 0.040 cm (Column 6, Lines 18-25).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of Kremer (US 4,635,488). Hung discloses all of the claimed limitations except a distal portion comprising an absorbent material, a tubular collection portion, a surface having molecules affixed that bind an agent in the ductal fluid, and a means to measure a quality of the ductal fluid. Kremer discloses a distal portion comprising an absorbent material, a tubular collection portion, a surface having molecules affixed that bind an agent in the ductal fluid, and a means to measure a quality of the ductal fluid (Figure 11). It would have been obvious to one with ordinary skill in the art to use the teachings of Kremer to modify the invention of Hung to create a probe with an absorbent collecting portion on the distal portion since it is notoriously well known in the art that an absorbent material is a means of collection of fluid.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of Kremer, further in view of Hung. Hung teaches all of the claimed limitations except a distal portion comprising means to measure a quality of the ductal fluid. Kremer teaches a distal portion comprising means to measure a quality of the ductal fluid (Figure 11). Hung et al discloses a quality of the ductal fluid that comprises an indicia or marker (Page 3, [0021]). Hung et al teaches that the cellular material that is collected from a human breast milk duct is a substance selected from the group consisting of whole cells, cellular debris, proteins, nucleic acids, polypeptides, glycoproteins, lipids, fats, glycoproteins, small organic molecules, metabolites, and macromolecules. It would have been obvious to one with ordinary skill in the art to use the teachings of Hung et al to modify the invention of Hung and Kremer to create a

device for collection of breast duct fluid that analyzes the different substances found in the ductal fluid.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of McDonald (US 5,844,251). Hung teaches all of the claimed limitations except a probe comprising MEMS. MacDonald et al discloses a probe wherein the distal portion comprises a MEMS (Column 2, Lines 52-67). MacDonald et al teaches that the MEMS on the probe is used in scanning tunneling microscopes, atomic force microscopes, mechanical positioning, as a magnetic field, electric field, capacitance, or van den Waals force detector. It would have been obvious to one with ordinary skill in the art to use the teachings of MacDonald et al to modify the invention of Hung in order to create a probe with a MEMS that is used to scan surfaces of the breast duct to measure surface configurations on the micron scale.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of McDonald, further in view of Hung. Hung et al discloses a quality of the ductal fluid that comprises an indicia or marker (Page 3, [0021]). Hung et al teaches that the cellular material that is collected from a human breast milk duct is a substance selected from the group consisting of whole cells, cellular debris, proteins, nucleic acids, polypeptides, glycoproteins, lipids, fats, glycoproteins, small organic molecules, metabolites, and macromolecules. It would have been obvious to one with ordinary skill in the art to use the teachings of Hung et al to modify the invention of Hung and Kremer to create a device for collection of breast duct fluid that analyzes the different substances found in the ductal fluid.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of Wilk (US 5,263,926). Hung teaches all of the claimed limitations except a probe that comprises a coating of an anesthetic on its exterior. Wilk teaches a probe that comprises a coating of an anesthetic on its exterior (Column 7, Lines 56-63). Wilk discloses that the anesthetic is applied on the exterior of the probe so that immediate temporary relief may be provided after completion of treatment. It would have been obvious to one with ordinary skill in the art to use the teachings of Wilk to modify the invention of Hung to create a probe with anesthetic on its outer surface to provide the patient with relief from possible discomfort due to treatment.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hung in view of Nita (US 5,382,228). Hung teaches all of the claimed limitations except a probe that comprises a shape memory material and is rigid before entry into the breast duct and flexible upon residence in the duct. Nita et al teaches a probe (24) with shape memory material (Column 6, Lines 32-34) that becomes more flexible during its time spent in the body. Nita et al discloses that devices made of shape memory material exhibit superelasticity consistently within the range of temperatures normally encountered during operation of the device. It would have been obvious to one with ordinary skill in the art to use the teachings of Nita et al to modify the invention of Kremer to create a probe that can change elasticity and become more flexible during its operation in the breast duct.

Response to Arguments

Applicant's arguments with respect to claims 1-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLT

December 16, 2002



MICHAEL J. HAYES
PRIMARY EXAMINER